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EXAMINER	
SINGH, SATYENDRA K	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,503	FISCHER, DAN E.	
	Examiner	Art Unit	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10,14,15 and 28-33* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10,14,15 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response and amendments to the claims filed with the office on June 29th 2007 is duly acknowledged.

Claims 16-27 have been cancelled by applicant's amendments to the claims.

Claims 11-13 (group II) remain withdrawn from further consideration.

Claims 1-4, 6-10, 14, 15 (as currently amended) and newly added claims 28-33 are examined on their merits in this office action.

This is a new ground of rejection necessitated by applicant's current amendments to the pending claims.

Claims Suggestions

1. Claims 2-4, 6-10 and 29-33 (as currently amended) recite "**An** implant device as recited in...". Applicants are advised to use "**The** implant device as recited in..." instead in order to properly limit the broader claims 1 and 28.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 30 recites the limitation of "**chopped cat**

gut", which is not described and supported in the instant disclosure as originally provided by applicants. There is no support or description for such a limitation in the instant disclosure, original claims, drawing, or the examples provided by applicants. The disclosure provided by applicants provide support for **ground or powdered cat gut** material as a thickener (see instant specification, page 11, [0033], in particular), but does not provide an explicit support or exemplification/disclosure for the "chopped cat gut" as a thickener. Since, the claimed invention is not fully supported by the disclosure either in the narrative or generic or in the examples or in the original claims provided by applicants, the claimed limitation constitutes a **new matter** situation. Appropriate explanation/correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 6-9 recite the limitation "**the delivery system**" in line 2. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-4, 6-10, 14, 15 and 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al (US 4,863,472; [D]) taken with Silverberg (US 4,755,184; [E]) in view of Levy (US 5,292,253; [A]) and Vyakarnam et al (US 6,306,424 B1; [F]).

Claims are generally directed to **an implant device** comprising a dry covering comprised of "a water absorbing gelatinizable material" (that becomes sticky and gelatinous upon contact with water), a "bone growth promoting material" (as recited in claim 1, as amended), wherein the dry covering forms an outer cover of the implant device so as to encapsulate the bone growth promoting material within an interior of the implant device (see instant claims 1-10, 14, and 15); and wherein the implant device comprises the bone growth promoting material in granular or powder form, and a thickener dispersed among said bone growth promoting material (see specific recitations of newly added claims 28-33).

Tormala et al [D] disclose an implant device comprising "water absorbing gelatinizable material" (a supporting structure suitable to work as a covering/encasing made of materials such as polyglycolide, **cellulose derivatives** or cross-linked **collagen** derivatives such as cat gut/**Katgut**; see Tormala et al, abstract; figures 1-2; columns 3-4; and column 4, lines 17-25, in particular) and a "bone growth promoting material" contained within said gelatinizable material (see Tormala et al, abstract and claims, in particular), wherein the water absorbing gelatinizable material is resorbable or non-resorbable, wherein bone growth promoting material is as specifically recited in

instant claim 5 (such as synthetic ceramic powders, or **hydroxyapatite** powder; see column 8, example 2, in particular), wherein the implant device has an elongated sausage-like or pillow like configuration (in the absence of any defined structural features/parameters in the claims for such "sausage-like" or "pillow-like configuration; see Tormala et al, figures 1-3 and column 5, 3rd paragraph, in particular), and a method of promoting bone growth comprising providing said implant device of claim 1, and placing the implant device adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Tormala et al, columns 5-6, in particular). In addition, Tormala et al disclose the fact that one can use or admix resorbable fibers, or polymer to bind (to work as a glue, i.e. used as a **thickener** that can form viscous gel upon contact with water) the bone graft particles together, if used as an additional inner resorbable supporting structure of the powder phase (see column 3, lines 1-2; column 4, last paragraph; and claim 9, in particular). Also disclosed in Tormala et al is the fact that the supporting structure (i.e. the covering) can be made of any shape or size (such as a bag or a flat tube; see abstract, column 6, lines 57-64, in particular) and the covering can be constructed in the form of a **woven or knitted** fibers (see column 5, lines 36-38, and claim 10, in particular).

Silverberg [E] discloses an implant device comprising "water absorbing gelatinizable material" (suitable to work as a covering material such as a casing made from polyglycolide in the form of a mesh, or collagen or cellulose; see abstract, summary of the invention, column 3, lines 31-55, and claims, in particular) and a "bone

growth promoting material" contained within said gelatinizable material (such as hydroxyapatite; see examples, column 4-5, in particular), wherein the water absorbing gelatinizable material is resorbable, wherein bone growth promoting material is hydroxyapatite powder, wherein the implant device has **an elongated sausage-like or pillow like configuration** (see figure1, in particular) and is gas sterilized prior to surgical applications (see column 5, 1st paragraph, in particular); and a method of promoting bone growth comprising providing said implant device of claim 1, and placing the implant device adjacent to bone tissue to be augmented, which is a void or defect resulting from the removal of tooth (i.e. alveolar ridge augmentation, and gingival repair; see Silverberg, column 4 and figure 3-5, in particular).

However, an implant device further comprising an adhesive such as **fibrin powder** (see instant claims 9-10); or a implant device, which is stored within **moisture-resistant packaging** is not explicitly disclosed by the referenced inventions of Silverberg and Tormala et al.

Levy [A] explicitly discloses the use of **fibrin** with or without collagen (see column 3, lines 24-29, and claims, in particular) to form a protein gel that can be combined with calcium-containing materials such as hydroxyapatite and/or calcium phosphate to prepare an implant used for filling the void or defects for the repair of tooth and bone tissues.

Vyakarnam et al [F] disclose the routine practice of packaging implant materials after sterilization in an appropriate sterilized, **moisture-resistant package** for shipment

and use in hospitals and other health care facilities (see column 19, 3rd paragraph, in particular).

Therefore, given the detailed disclosures of the components and the structure of the implant device (as claimed in the instant application) in the above cited prior art references, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the implant device taught by Tormala et al (taken with the disclosure of Silverberg) such that it further comprises an adhesive such as fibrin, and is stored within a moisture-resistant packaging as explicitly suggested and demonstrated by the disclosures of Levy and Vyakarnam et al with a reasonable expectation of success in order to provide a gelling component or a glue in the composition as well as to avoid contamination of the implant device during storage (both the limitations are deemed to be routinely practiced in the implantation art).

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Response to Applicant's Arguments

Applicant's arguments filed on June 29th 2007 (as they pertain to the prior art rejection of record) have been fully considered but they are not persuasive for the following reasons of record.

Applicant's argument with regards to the 103(a) rejection of record that the amended claim 1 requires a "*dry covering*" made of material "*that becomes sticky and gelatinous upon contact with water" and that encapsulates the bone growth promoting material*", and none of the references alone or in combination teach or suggest the claimed invention when viewed as a whole (see response, page 10, first paragraph, in particular) has been considered by was not persuasive because the cited prior art reference, Tormala et al discloses natural polymeric materials (such as Katgut, collagenous material or cellulose derivatives such as Surgicel, an oxidized cellulose that are dry and become sticky and gelatinous upon contact with water; see Tormala et al, column 4, 2nd paragraph, in particular) for the covering structure (that can be made in the shape of box, tube or bag; see abstract, in particular) that forms an enclosure (i.e. encapsulates "an interior", at least to some extent, in the form of a chute or bag or tube) for the bone growth promoting material (i.e. hydroxyapatite powder) within the covering. In addition, the argument that Silverberg appears to teach away from a covering that becomes sticky and gelatinous upon contact with water (see response, page 10, 1st paragraph, last three lines, in particular) is not found to be persuasive because Silverberg clearly discloses the fact that the "hollow casing" used to encapsulate the bone growth material (see abstract, in particular) can be constructed from polymeric

materials such as bovine collagen (see Silverberg, column 3, lines 44-46, in particular) that is dry and will become "sticky and gelatinous upon contact with water".

Since, all the components recited in claims 1-4, 6-10, 14, 15, and 28-33 have been disclosed and/or suggested, in details, in the cited prior art references for an implant device (including the method of using such an implant device in a patient as recited in instant claims 14 and 15) such as claimed in the instant invention, the obviousness rejection of record is deemed proper and is maintained.

Conclusion

NO claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Satyendra K. Singh
Patent Examiner
Art unit 1657

IRENE MARY
PRIMARY EXAMINER